Genzyme
Regulatory Affairs

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Dockets Management Branch,
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 99D-2726

Dear Sir or Madam:

Genzyme Corporation hereby submits its written comments on the draft guidance entitled "Medical Devices: Draft Guidance on Labeling for Laboratory Tests". Genzyme appreciates the opportunity to comment on this document. Genzyme is a leading manufacturer of pharmaceuticals, biologics, devices and *in vitro* diagnostic products (IVD's).

First, it is not apparent from the title of this document the purpose or intent of what the document is to accomplish. After reading the Federal Register background and the document itself, it became clear that this is not a comprehensive guidance on IVD labeling. Instead it focuses on the issue of performance terminology which *may* appear in some IVD labels. A guidance should provide industry, FDA, and consumers with clear, well-defined messages based on the agency's current thinking about medical devices. As such it would be helpful to have a detailed background discussion on what is the proposed intended use of the document and a rationale as to why it is needed. *Since this document and the background material is not clear, Genzyme's comments, which follow, are based on the assumptions that:*

(a) the agency is proposing a guidance to address terminology which may be utilized in the evaluation of premarket applications and

(b) *Proposing definitions of terminology which may possibly used in satisfying 21CFR 809.10(b)(12) concerning disclosure in the labeling of specific performance characteristics.*

Genzyme's specific comments are as follows:

- Under "Proposed Labeling", the first bullet in point 1, the suggestion is made that ROC curves are appropriate and may be used. Genzyme agrees that this is technically correct. However, very few laboratories and even fewer health care givers understand ROC curves as measures of performance. If the agency is recommending them as useful information, the agency should be prepared to educate the consumer about their use.

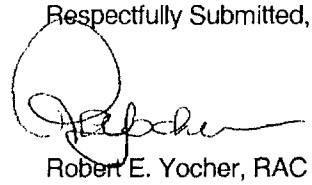
- Under the third and fourth bullet in point 1, Genzyme believes the guidance should require a discussion of prevalence and predictive values whenever a sensitivity and specificity claim is made. Simply knowing specificity and sensitivity without knowing the prevalence of the test population versus the true clinical population seen by that practitioner is misleading.

- The title of the Guidance should be changed to accurately reflect the content.

- The FDA, in cooperation with NCCLS, CAP, or CDC, should conduct an educational campaign directed at the consumer on measures of performance of laboratory tests. While Genzyme agrees that the guidance describes the correct scientific terminology to assess performance criteria for some IVD's, consumers will not be comfortable with co-positivity, co-negativity or ROC curves in describing performance characteristics. A standard glossary of terms accepted by the entire medical community is needed. Due to global regulatory requirements for labeling, manufacturers do not have label space to add a glossary or explain the use of these terms. If these terms are utilized and not understood, the labeling may become misleading.

In conclusion, Genzyme believes this draft guidance should be withdrawn. DCLD should define the problem, clearly state the goals intended to be addressed by the guidance, and then invite all stakeholders to participate in the formulation of a new guidance.

Respectfully Submitted,



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